10/164,177

## What is claimed is:

1 1. An enveloped pharmaceutical composition comprising:

a first active available for immediate release; and

a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof,

wherein the first and the second active are disposed on separate carriers.

- 1 2. The composition of claim 1, wherein the first and second actives are enveloped in
- 2 a single dose.
- 1 3. The composition of claim 1, wherein the first and second actives are enveloped
- 2 into a single dose.
- 1 4. The composition of claim 1, wherein the first and second actives are packed into a
- 2 capsule, caplet, softgel, gelcap, suppository, film, granule, gum, insert, pastille, pellet,
- 3 troche, lozenge, disk, poultice or wafer.
- 1 5. The composition of claim 1, wherein over 80% of the first active is released
- 2 within about 60 minutes.
- 1 6. The composition of claim 1, wherein immediate release is defined further as
- 2 comprising release of over 90% of the first active within about 90 minutes.
- 1 7. The composition of claim 1, wherein extended release is defined further as
- 2 comprising release of over 80% of the second active within about 60 minutes to about 8
- 3 hours.
- 1 8. The composition of claim 1, wherein extended release is defined further as
- 2 comprising release of over 90% of the second active within about 90 minutes to about 6
- 3 hours.
- 1 9. The composition of claim 1, wherein the first active comprises gauifenesin.
- 1 10. The composition of claim 1, wherein the first active comprises gauifenesin DC in
- 2 a powder form.

1 11. The composition of claim 1, wherein the first active comprises 211 mg of 95%

- 2 gauifenesin.
- 1 12. The composition of claim 1, wherein the second active comprises a nasal
- 2 decongestant.
- 1 13. The composition of claim 1, wherein the second active comprises phenylephrine.
- 1 14. The composition of claim 1, wherein the second active comprises phenylephrine
- 2 as a sustained release bead.
- 1 15. The composition of claim 1, wherein the second active comprises phenylephrine
- 2 as a layered sustained release bead.
- 1 16. The composition of claim 1, wherein the second active comprises three or more
- 2 layers of phenylephrine on a bead.
- 1 17. The composition of claim 1, wherein the first active is superposed on the second
- 2 active.
- 1 18. The composition of claim 1, comprising further one or more inactives.
- 1 19. The composition of claim 1, wherein the first active for immediate release
- 2 comprises a powder form and the second active comprises a beaded form.
- 1 20. An enveloped pharmaceutical composition comprising:
- a first active available for immediate release; and
- a second active available for extended release, wherein the first active effects a
- 4 physiological result that improves the physiological action of the second active upon
- 5 extended release.
- 1 21. The composition of claim 20, wherein the first and second actives are enveloped
- 2 in a single dose.
- 1 22. The composition of claim 20, wherein the first and second actives are enveloped
- 2 into a single dose.

1 23. The composition of claim 20, wherein the first and second actives are packed into

- a capsule, caplet, softgel, gelcap, suppository, film, granule, gum, insert, pastille, pellet,
- 3 troche, lozenge, disk, poultice or wafer.
- 1 24. The composition of claim 20, wherein over 80% of the first active is released
- 2 within about 60 minutes.
- 1 25. The composition of claim 20, wherein immediate release is defined further as
- 2 comprising release of over 90% of the first active within about 90 minutes.
- 1 26. The composition of claim 20, wherein extended release is defined further as
- 2 comprising release of over 80% of the second active within about 60 minutes to about 8
- 3 hours.
- 1 27. The composition of claim 20, wherein extended release is defined further as
- 2 comprising release of over 90% of the second active within about 90 minutes to about 6
- 3 hours.
- 1 28. The composition of claim 20, wherein the second active for extended release is
- 2 selected from the group consisting of a decongestant, an antihistamine, an expectorant, an
- 3 antitussive and mixtures thereof.
- 1 29. The composition of claim 20, wherein the first active comprises gauifenesin.
- 1 30. The composition of claim 20, wherein the first active comprises Gauisenesin DC
- 2 in a powder form.
- 1 31. The composition of claim 20, wherein the first active comprises 211 mg of 95%
- 2 gauifenesin.
- 1 32. The composition of claim 20, wherein the second active comprises a nasal
- 2 decongestant.
- 1 33. The composition of claim 20, wherein the second active comprises phenylephrine.
- 1 34. The composition of claim 20, wherein the second active comprises phenylephrine
- 2 as a sustained release bead.

1 35. The composition of claim 20, wherein the second active comprises phenylephrine

- 2 as a layered sustained release bead.
- 1 36. The composition of claim 20, wherein the second active comprises three or more
- 2 layers of phenylephrine on a bead.
- 1 37. The composition of claim 20, wherein the first active is superposed on the second
- 2 active.
- 1 38. The composition of claim 20, comprising further one or more inactives.
- 1 39. The composition of claim 20, wherein the first active for immediate release
- 2 comprises a powder form and the second active comprises a beaded form.
- 1 40. An enveloped pharmaceutical composition comprising:
- a first active packaged so that over 90 % of the first active is released within about
- 3 90 minutes; and
- 4 a second active for extended release selected from the group consisting of a decongestant,
- 5 an antihistamine, an expectorant, an antitussive and mixtures thereof, wherein over 90%
- 6 of the second active is released between about 1 and 6 hours.
- 1 41. The composition of claim 40, wherein the first and the second actives are
- 2 disposed on separate carriers.
- 1 42. The composition of claim 40, wherein the first and second actives are enveloped
- 2 in a single dose.
- 1 43. The composition of claim 40, wherein the first and second actives are enveloped
- 2 into a single dose.
- 1 44. The composition of claim 40, wherein the first and second actives are packed into
- 2 a capsule, caplet, softgel, gelcap, suppository, film, granule, gum, insert, pastille, pellet,
- 3 troche, lozenge, disk, poultice or wafer.
- 1 45. The composition of claim 40, wherein over 80% of the first active is released
- 2 within about 60 minutes.

1 46. The composition of claim 40, wherein immediate release is defined further as

- 2 comprising release of over 90% of the first active within about 60 minutes.
- 1 47. The composition of claim 40, wherein extended release is defined further as
- 2 comprising release of over 80% of the second active within about 60 minutes to about 8
- 3 hours.
- 1 48. The composition of claim 40, wherein extended release is defined further as
- 2 comprising release of over 90% of the second active within about 90 minutes to about 6
- 3 hours.
- 1 49. The composition of claim 40, wherein the first active comprises gauifenesin.
- 1 50. The composition of claim 40, wherein the first active comprises gauifenesin in a
- 2 powder form.
- 1 51. The composition of claim 40, wherein the first active comprises 211 mg of 95%
- 2 gauifenesin.
- 1 52. The composition of claim 40, wherein the second active comprises a nasal
- 2 decongestant.
- 1 53. The composition of claim 40, wherein the second active comprises phenylephrine.
- 1 54. The composition of claim 40, wherein the second active comprises phenylephrine
- 2 as a sustained release bead.
- 1 55. The composition of claim 40, wherein the second active comprises phenylephrine
- 2 as a layered sustained release bead.
- 1 56. The composition of claim 40, wherein the second active comprises three or more.
- 2 layers of phenylephrine on a bead.
- 1 57. The composition of claim 40, wherein the first active is superposed on the second
- 2 active.
- 1 58. The composition of claim 40, comprising further one or more inactives.

- The composition of claim 40, wherein the first active for immediate release comprises a powder form and the second active comprises a beaded form.

  An enveloped pharmaceutical composition comprising:

  a first active available for immediate effervescent release; and
- a second active for extended release in a mini-tab selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof.
- 1 61. An enveloped pharmaceutical composition comprising:
- a first active available for immediate release; and
- a second active for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof wherein the first and second actives are different.
- 1 62. An liquid pharmaceutical composition comprising:
- 2 a first active available for immediate release; and
- a second active coated on or about one or more suspended beads for extended release selected from the group consisting of a decongestant, an antihistamine, an expectorant, an antitussive and mixtures thereof, wherein the first active effects a physiological result that improves the physiological action of the second active upon extended release.
  - 63. The liquid pharmaceutical composition of claim 62, wherein the first and second active are made available in a solution, suspension, cream, ointment, lotion, enema, elixir, syrup, emulsion, gum, insert, jelly, foam, paste, pastille, spray, magma or poultice.
  - A method of loading one or more actives on a bead for extended release comprising:
- adding a first active onto one or more beads with an adhesive and a sustained
   release coating; and
- adding a extended release coating prior to or in combination with a second active.

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## **PATENT** The method of claim 62, wherein the adhesive comprises a pharmaceutical glaze. The method of claim 62, wherein the adhesive is a sustained release coating that is added prior to the addition of the first active. 2 The method of claim 62, wherein the adhesive is a sustained release coating that 1 is added concurrent with the addition of the first active. 2 The method of claim 62, wherein the adhesive is a sustained release coating is about or after the addition of the first active. 2 The method of claim 62, wherein the adhesive is a sustained release coating is mixed with the first active, and the mixture is added onto one or more beads. 2 The method of claim 67, wherein the bead comprises a portion of a mini-tab. The method of claim 62, further comprising the step of adding an erosion matrix. The method of claim 62, further comprising the step of adding one or more 2 inactives. A method of loading an active into a mini-tab to be encapsulated for extended release, using an erosion matrix. 2 A method of providing a dual-release formulation comprising: a first active in a powered form and a second active in an extended release form, 2 wherein the first and second actives are loaded into a capsule. 3 A method of loading an active on a bead comprising: 1 adding the active onto one or more beads with a pharmaceutical glaze; 2 curing the active and the glaze for between about 3 to 6 hours prior to adding a 3

The method of claim 73, wherein the active comprises a decongestant.

repeating the steps of adding active and curing the active at least two more times.

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sustained release coating; and

	PATENT PHFB:1007
1	A method of providing a dual-release formulation comprising:
2	providing a first active comprising an expectorant packed for immediate release in
3	a powder form;
4	providing a second active comprising a nasal decongestant packed for extended
5	release on a bead, and
6	enveloping the first and the second actives, wherein the first active provides
7	productive coughs in the short-term and the second active provides long acting
8	decongestant activity.
1	A method of providing a dual-release formulation comprising:
2	providing a first active comprising an expectorant packed for immediate release in
3	a powder form;
4	providing a second active comprising a nasal decongestant packed for extended
5	release on a bead, and
6	encapsulating the first and the second actives, wherein the first active provides
7	productive coughs in the short-term and the second active provides long acting
8	decongestant activity.
1	A method of providing a dual-release formulation comprising:
2	providing a first active comprising an expectorant packed for immediate release in
3	a powder form;

active provides productive coughs in the short-term and the second active provides long

providing a second active comprising a nasal decongestant packed for extended

suspending the first and the second actives in a liquid medium, wherein the first

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release on a bead, and

acting decongestant activity.